

REMARKS

This document is submitted in response to the Office Action dated September 28, 2006 ("Office Action").

Applicants have canceled claims 27 and 28. Claims 24-26 were previously canceled.

Upon entry of the proposed amendments, claims 15-23 will be pending. In view of the following remarks, reconsideration of the claims is respectfully requested.

Anticipation

Claims 15-19, 21-23 and 27-28 remain rejected as being anticipated by Lesens et al., US Patent 6,399,124 ("Lesens") and Sobol et al., US Patent Application 2003/0235559 ("Sobol") on the same ground. See the Office Action, page 3, lines 6-8, and page 6, lines 3-5. Claims 27 and 28 have been canceled.

The rejected claims are directed to the *Lactobacillus gasseri* strains B21T1, B21T6, C21T1, X21B7, and B38T38 and the *Lactobacillus acidophilus* strain B6T7, their subcultured offspring, as well as food products and pharmaceutical compositions containing these strains.

According to the Examiner, Lesens discloses a frozen dessert containing *Lactobacillus acidophilus* and *Lactobacillus gasseri* bacteria. See page 3, lines 9-14. He also states that Sobol discloses the use of *Lactobacillus acidophilus* and *Lactobacillus gasseri* bacteria to lower cholesterol. See page 6, lines 6-16. Neither reference discloses any of B21T1, B21T6, C21T1, X21B7, B38T38, or B6T7.

It is undisputed, and the Examiner does not assert otherwise, that Lesens and Sobol do not disclose any of the six specifically recited *Lactobacillus* strains, B21T1, B21T6, C21T1, X21B7, B38T38, and B6T7. Instead, the Examiner contends that Lesens and Sobol inherently anticipate the rejected claims, since both references allegedly disclose *Lactobacillus* strains that possess the same characteristics as the six strains. See the Office Action, page 3, lines 15-17, and page 6, lines 22-24. Applicants respectfully disagree.

As MPEP 2112 states, the Examiner "...**must** provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (bold face added)." Further, the Examiner establishes a prima facie case for inherent anticipation "[w]here the claimed and prior art products are identical or substantially identical in structure or composition." MPEP 2112.01. In other words, the Examiner has the burden to show that the alleged prior art strains and any of the six claimed strains, B21T1, B21T6, C21T1, X21B7, B38T38, and B6T7, are identical in structure or composition, so a skilled person could reasonably conclude that the strains possess the same inherent characteristics.

However, the Examiner **fails** to carry her burden to establish a prima facie case of inherent anticipation, for the simple reason that neither Lesens nor Sobol discloses at least one **identifiable** *Lactobacillus gasseri* or *Lactobacillus acidophilus* strain with **disclosed** structure or composition that can be compared to the six claimed strains. She has not pointed to a single strain that is described by its deposit number, genetic mutations, molecular phenotypes, functional phenotypes, or other relevant information that would allow a skilled person to conclude that the strain is indeed identical in structure or composition to any of the six claimed strains. In the absence of any supporting information, the Examiner's ground for asserting inherent anticipation depends entirely on the **flawed reasoning** that all *Lactobacillus* strains necessarily have the same characteristics merely because they are *Lactobacillus* strains, regardless of any genetic variations among different strains. Such reasoning is clearly unattainable, and compels the conclusion that the Examiner has **improperly** asserted inherent anticipation against the rejected claims reciting the six strains, B21T1, B21T6, C21T1, X21B7, B38T38, and B6T7.

To further support the conclusion that the Examiner has improperly asserted inherent anticipation, Applicants would like to address particular issues raised in the Office Action.

First, the Examiner mistakenly cites MPEP 2131.02, which states that "[a] generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus," as a ground for rejection. See the Office Action, page 5, lines 16-18. The rejected

claims in fact recite species that may fall within the genus disclosed in the two references, as the claims recite six **specific (i.e. species)** *Lactobacillus gasseri* and *Lactobacillus acidophilus* strains, where as Lesens and Sobol only disclose *Lactobacillus gasseri* and *Lactobacillus acidophilus* in **general (i.e. genus)**. The applicable MPEP 2131.02 guidelines, therefore, should be that “[a] genus does not always anticipate a claim to a species within the genus.” MPEP 2112 further states that "...[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category' but must be examined to see if a disclosure of the claimed species has been made..." In other words, Lesens and Sobol do not necessarily anticipate the rejected claims, and the Examiner fails to demonstrate otherwise for the reasons already set forth above.

Second, the Examiner's statement that "[b]y all comparable data the *Lactobacillus gasseri* and *Lactobacillus acidophilus* of the prior art are the instantly claimed sub-cultured offspring thereof or a mutant derived therefrom because they are the same genus and specie" has no basis in fact or reasoning. Applicants question the existence of any "comparable data," since the Examiner fails to cite any specific paragraphs, tables or figures from any references that describe such data. Further, the Examiner fails to point to any paragraphs, tables or figures in either Lesens or Sobol that discloses any *Lactobacillus gasseri* or *Lactobacillus acidophilus* strains that are derived from B21T1, B21T6, C21T1, X21B7, B38T38, or B6T7. Moreover, there is absolutely no scientific basis for the Examiner's assertion that strains of the same genus and species must be mutants or subcultured offspring of each other.

Third, the Examiner's request for comparative data between Applicants' six strains and other strains is **improper**, since she has not carried her **initial burden** to establish a prima facie case of inherent anticipation as set forth above. See the Office Action, page 5, lines 4-10. Thus, to require additional data now is **premature** and contrary to the guidelines set forth in MPEP 2112, although Applicants attempted in good faith to accommodate the Examiner's request in the last reply. Applicants would be glad to provide additional data **after** the Examiner has satisfied her burden.

Lastly, the Examiner **does not identify** any alleged prior art strains, and yet insists on side-by-side comparative data between the six claimed strains and these **unidentified** prior art strains. See the Office Action, page 5, lines 4-10. As repeatedly set forth above, neither Lesens nor Sobol identifies any specific *Lactobacillus gasseri* or *Lactobacillus acidophilus* strains for comparison. The best Applicants can do, and have done so in the last reply, is to point to comparative data between Applicants' six strains and other publicly available *Lactobacillus gasseri* and *Lactobacillus acidophilus* strains. See the Specification, e.g., page 36, Table 5. The data clearly demonstrates that, contrary to the Examiner's ground for rejection, not all *Lactobacillus* strains necessarily have the same inherent characteristics. However, the Examiner rejects the data on the ground that Applicants have not pointed out which strains are the alleged prior art strains disclosed in Lesens or Sobol. See the Office Action, page 8, lines 4-10. Applicants have not done so for the simple reason that no such alleged prior strains are disclosed in Lesens or Sobol. Applicants further submit that it is the **Examiner's burden** to clearly identify prior art strains that allegedly possess the same characteristics as the claimed strains. As Examiner does not identify specific prior art strains, Applicants are at a loss as to how she can assert a prima facie case of inherent anticipation.

In view of the above remarks, Applicants submit that claims 15-19, and 21-23 are not anticipated by Lesens or Sobol. Withdrawal of the rejection is respectfully requested.

Indefiniteness

The Examiner rejects claims 15, 27 and 28 as being indefinite. See the Office Action, page 9, lines 7-9. Applicants have canceled claims 27 and 28, mooted the rejection.

As the Examiner does **not** state the ground for rejecting claim 15, it is not apparent as to why the claim is indefinite. Applicants can only note that, since claim 15 recites six specific deposited *Lactobacillus gasseri* and *Lactobacillus acidophilus* strains, as well as their subcultured offsprings, they indeed particularly point out and distinctly claim the subject matter of Applicants' invention. If the Examiner means to assert that the term "subcultured offspring"

is indefinite, Applicants note that a skilled person would understand the term to refer to a culture derived from any of the six claimed deposited strains.

Claim objection

Claim 20 is objected to as being dependent indirectly from rejected claim 15. See the Office Action, page 9, line 5.

As the ground for rejecting claim 15 has been overcome for the reasons set forth above, Applicants respectfully request that the Examiner withdraw the objection.

CONCLUSION

In view of the foregoing remarks, Applicant submits that all pending claims are novel, definite and not objectionable. Allowance of the application is proper, and an early favorable action is respectfully solicited.

The petition fee in the amount of \$60 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 16640-002001. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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